



DEPARTMENT OF HEALTH & HUMAN SERVICES

D1379B
Public Health Service

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

January 28, 1998

WARNING LETTER

SJN-98-07

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William E. Ronca
President & Owner
SOS Technologies
Division of Caribbean Medical Products, Inc.
15-6 Calle Granada URB Torrimar
Guaynabo, PR 00966

Dear Mr. Ronca:

During an inspection of your compressed medical gas transfilling facility, SOS Technologies, conducted from January 7 to 14, 1998, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's transfilling of Oxygen, U.S.P. causing this drug product to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to adequately test or take other appropriate measures to assure the quality and potency of incoming compressed Oxygen, U.S.P. as required by 21 CFR 211.84 (d)(2) in that the firm does not conduct routine audits of the supplier to assure that certificates of analysis received with incoming shipments represent valid sampling and testing results.
2. Failure to perform adequate testing of the finished product, filled vessels of Oxygen, U.S.P. compressed gas, in accordance with 21 CFR 211.165 (a) in that no potency testing is performed on the filled vessels before distribution.
3. Failure to adequately test drug product containers in accordance with 21 CFR 211.84 in that the vessels which are returned from customers to be refilled with Oxygen, U.S.P. are not evacuated by means of a vacuum pump capable of pulling a vacuum of 25 inches of mercury at sea level or other suitable means to assure that any contaminants which might be present are removed.

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4. Failure to record on the batch production records each significant step in the filling of Oxygen, U.S.P. compressed gas into smaller vessels in accordance with 21 CFR 211.188 (b) in that check of the hydrostatic test dates for the cylinders, external examination of the cylinders, results of sniff or odor test of the empty cylinders, valve assembly examination and venting operations on the empty cylinders are not recorded. In addition, the filling temperature and pressure, heat compression checks and valve leak testing results on filled cylinders are also not included in the batch records.
5. Inadequate laboratory record keeping procedures as required by 21 CFR 211.192 (d) in that there is no record that testing equipment such as the MiniOx oxygen analyzer and the oxygen pressure gauge are calibrated as appropriate.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

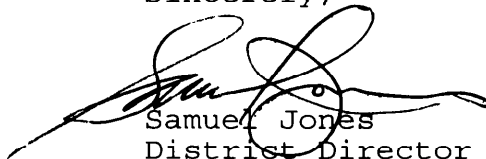
Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory actions without further notice. These include seizure and/or injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,



Samuel Jones
District Director